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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WILSON, MICHAEL C	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/803,578	HWU ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-8,10,11,40,41 and 44-70* is/are pending in the application.

4a) Of the above claim(s) *62-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-8,10,11,40,41 and 44-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 5, 12, 15, 43 have been cancelled. Claims 44-70 have been added. Claims 1, 3, 4, 6-8, 10, 11, 40, 41 and 44-70 are pending.

Election/Restrictions

Applicants elected Group I, the species of an ovarian tumor antigen and a chimeric receptor that is an Mov-γ receptor on 9-9-02.

Newly submitted claims 62-70 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim 62 relates to an isolated/purified human lymphocyte having a chimeric receptor that reacts with a tumor antigen and a TCR that reacts with an antigen that is not a tumor antigen.

Claim 70 relates to a method of making human lymphocytes having dual antigen specificity by i) contacting human lymphocytes with an antigen that is not a tumor antigen, and ii) transducing the lymphocyte with a chimeric receptor that reacts with a tumor antigen.

Claims 62 and 70 are drawn to non-elected invention of Group II. Claims 62 and 70 require the second receptor reacts with a non-tumor antigen while Group II requires the second receptor reacts with viral antigens. When read in light of the specification, the only other non-tumor antigen disclosed in the specification and recognized by the second receptor is a viral antigen. Therefore, claims 62 and 70 will not be considered because they are part of non-elected Group II.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Claims 62-70 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 3, 4, 6-8, 10, 11, 40, 41 and 44-61 are under consideration in the instant office action. Applicant's arguments filed 12-29-03 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 is under consideration in the instant office action as it relates to a lymphocyte having i) an Mov-γ receptor or a T-cell receptor (TCR) that reacts with an ovarian tumor antigen, and ii) an "endogenous" TCR that reacts with a cell that is allogeneic to the lymphocyte.

Claim 11 is under consideration as it relates to a lymphocyte having i) a TCR that reacts with a cell that is allogeneic to the lymphocyte, and ii) an Mov-γ receptor that reacts with an ovarian tumor antigen.

Claim 40 is under consideration as it relates to a pharmaceutical composition comprising lymphocytes having i) an Mov-γ receptor reactive with an ovarian tumor antigen, and ii) an "endogenous" TCR that reacts with a cell that is allogeneic to the lymphocyte.

Claim 41 is under consideration as it relates to a method of preparing lymphocytes having dual antigen specificity by i) contacting lymphocytes with a cell that

is allogeneic to the lymphocyte, and ii) transducing the lymphocyte with an Mov-γ that reacts with an ovarian tumor antigen.

Specification

The status of application 08/547263, cited on pg 17, line 5, needs updated prior to allowance as necessary.

Claim Rejections - 35 USC ' 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

I. Claims 1, 3, 4, 6-8, 10, 11, 40, 41 and 44-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The scope of lymphocytes having a second receptor that recognizes any cell that is allogeneic to the lymphocyte is new matter (1, 11, 40, 41). Applicants point to Examples 3-8, which only teach stimulating the cells with PBMC and determining if the cells recognize allogeneic PBMC (Fig. 9). The specification does not teach the receptor will recognize any allogeneic cell as broadly claimed.

The phrase "dual antigen specificity" is new matter (41). Applicants point to pg 31, ¶ 80, line 12, which only teaches "dual specificity T cells" inhibited tumors. The citations does not teach the T cells had "antigen specificity" as claimed, especially specific to one antigen found on allogeneic PBMC.

The lymphocyte having two receptors comprising 1) an Mov-γ receptor, and 2) an endogenous receptor that reacts with splenocyte, dendritic cell or peripheral blood cell that is allogeneic to the lymphocyte (claims 46, 50, 56 and 58) is new matter. Applicants point to pg 29, lines 7-13 of ¶ 77 and pg 30, line 3 of ¶ 79. Pg 29, lines 7-13 of ¶ 77 teaches immunizing mice with allogeneic splenocytes or dendritic cells to stimulate lymphocytes. It does not teach the splenocytes or dendritic cells were recognized by any lymphocytes isolated from the mice or that lymphocytes isolated from the mice had receptors that reacted with splenocytes or dendritic cells were present on the lymphocytes. Most importantly, the lymphocytes do not express an Mov-γ receptor as claimed. Pg 30 teaches mice having dual specific T-cells expressing Mov-γ were injected subcutaneously with allogeneic splenocytes. It does not teach the T-cells and splenocytes were in contact or that the T-cells had a receptor that reacted with the splenocytes as required in the claims. It appears that the T-cells were already "dual specific" before stimulation with the allogeneic splenocytes, but the claim is describing the second of the two receptors as being reactive with allogeneic splenocytes.

II. Claims 1, 3, 4, 6-8, 10, 11, 40, 41 and 44-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The

claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The "chimeric receptor reactive with a tumor antigen" lacks written description. An adequate written description of a chimeric receptor requires a description of the nucleic acid sequence encoding the chimeric receptor because the protein is made by genetic modification. Adequate written description of a nucleic acid sequence encoding a chimeric receptor that recognizes tumor antigens requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. It is not sufficient to define DNA solely by its principal biological property, i.e. recognizing tumor antigen because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any DNA with that biological property.

The only chimeric receptor taught in the specification that recognizes a tumor antigen as in claims 1, 11, 40 and 41 is the Mov-γ receptor. The specification does not teach the nucleic acid sequence of antibody or T-cell receptor fragments that recognize tumor antigens. The specification does not teach how the Mov-γ receptor was made so that other chimeric receptors having equivalent structures and functions could be made. The specification does not correlate the nucleic acid sequences encoding antibody fragments used to create the Mov-γ receptor to any other nucleic acid sequences known in the art that encoded antibody fragments that recognized tumor antigens. The nucleic acid sequence encoding the Mov-γ receptor is one species in a multitude of

possible "chimeric receptors" that recognize a tumor antigen and is not adequate written description for the genus which encompasses any type of receptor (e.g. antibody, T-cell receptor, insulin receptor, cholesterol receptor, etc.) that reacts with any type of tumor antigen (e.g. MART, CEA, FBP, etc).

Thus, claiming a lymphocyte having a chimeric receptor that recognizes a tumor antigen without teaching the nucleic acid sequence encoding the fragments that are essential to make the chimeric receptor is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). With respect to the method claims, adequate description of the methods first requires an adequate description of the materials, i.e. specific DNA sequences, which provide the means for practicing the invention.

Claims 1, 3, 4, 6-8, 10, 11, 40 and 41 remain rejected and claims 44-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

The metes and bounds of claim 1 are unclear. It is unclear if the "chimeric receptor or a T-cell receptor, either of which is reactive with a tumor antigen" may also be the "endogenous T-cell receptor reactive with a cell, which is allogeneic to the lymphocyte". Thus, it is unclear whether the claim is limited to a lymphocyte having two

receptors or if the claim encompasses a lymphocyte having one receptor that fits both descriptions.

The term "endogenous T-cell receptor" is unclear. It is unclear if the phrase is limited to T-cell receptors that are introduced exogenously into the lymphocyte, or if the phrase encompasses receptors introduced by recombinant technology. Receptors introduced by recombinant technology may be encompassed by the claims because such receptors originate or are produced by the lymphocyte (See Stedman's Medical dictionary definition of "endogenous" enclosed). If the claim is limited to two receptors, the structure and function of the receptors is not clearly set forth.

Use of a "chimeric receptor" or a "T-cell receptor" that recognizes a tumor antigen together in claim 1 a) does not make sense. At first glance, it appears that the chimeric receptor is a species of the T-cell receptor because a chimeric receptor that recognizes a tumor antigen must be a T-cell receptor. But why would a species be listed with a genus instead of being used in a dependent claim to further limit the genus? One would then wonder if applicants were attempting to include two receptors having different scopes in claim 1 a). Thus, one of skill is left wondering whether the two receptors in claim 1 a) are related as species/genus or if they are two species having overlapping subject matter. The structural or functional distinction between the two receptors in claim 1 a) is unclear.

Use of a "T-cell receptor" that recognizes an antigen together with a "T-cell receptor" that recognizes a cell in the same claim does not make sense because an antigen is only recognized in context of a cell and a cell is only recognized by a T-cell

receptor using an antigen on the surface of that cell. The structural or functional distinction between the T-cell receptor recognizing an antigen in claim 1 a) and the endogenous T-cell receptor recognizing a cell in claim 1 b) cannot be determined.

The phrase "an endogenous T-cell receptor reactive with a cell, which is allogeneic to the lymphocyte" in claims 1, 11, 40 is indefinite. It is unclear if the phrase "which is allogeneic to the lymphocyte" relates to the cell or the T-cell receptor. The phrase "a cell that is allogeneic to the lymphocyte" would overcome this rejection.

The metes and bounds of claims 4, 10, 48, 51, 53, 54, 57, 59 are indefinite. It is unclear if the chimeric Mov receptor is an ovarian tumor antigen because claim 10 claims the chimeric Mov receptor further limits the ovarian tumor antigen of claim 4.

The metes and bounds of claim 11 are unclear. It is unclear if the "chimeric receptor reactive with a tumor antigen" may also be the "T-cell receptor reactive with a cell, which is allogeneic to the lymphocyte". Thus, it is unclear whether the claim is limited to a lymphocyte having two receptors or if the claim encompasses a lymphocyte having one receptor that fits both descriptions.

The rejection of claim 4 regarding clearly set forth the tumor antigen is an ovarian tumor antigen has been withdrawn in view of the amendment to claim 4.

The metes and bounds of the term " Mov-γ" in claim 10 and in new claims 51, 53, 57 remain unclear. It is unclear if the term is generic to any chimeric receptor having a variable region of a monoclonal antibody and a T-cell receptor γ chain (pg 8, line 4) or if it is limited to a chimeric receptor having a variable region of a monoclonal antibody and a T-cell receptor γ chain that is specific to ovarian tumor antigen (pg 27, line 2).

Applicants repeat the previous argument that the term was known in the art at the time of filing (Hwu et al., 1993, J. Exp. Med., Vol. 178, pg 361-366 and Hwu et al., Cancer Res., Vol. 55, pg 3369-3373). Again Applicants' argument is not persuasive for reasons of record. Those reasons are repeated in the remainder of the paragraph. Hwu et al. 1993 taught Mov-γ was a chimeric receptor was made using an scFv from Mov18, a mAb that is relatively specific for human ovarian carcinoma on pg 362, col. 2, 3rd paragraph, but does not teach the structure of the scFv from Mov18 or the elements combined with the scFv to make the Mov-γ receptor. Neither the specification nor the art at the time of filing limits Mov-γ to being a chimeric receptor having an scFv from Mov18. It is unclear if Mov-γ is limited to a chimeric receptor having an scFv from Mov18, antibody fragment that recognizes folate-binding protein or a mAb that is relatively specific for human ovarian carcinoma.

The phrase "dual antigen specificity" is indefinite (claim 41). It unclear to what two antigens the lymphocytes are specific. Only one receptor is required that reacts with an antigen. Neither the "reaction" to the cell or the antigen are "specific."

Claim Rejections - 35 USC ' 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

> only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3, 4, 6-8, 10, 11, 40, 41 remain rejected and claims 44-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Nishimura (US Patent 5,830,755) as supported by the definition of "allogeneic" in Dorland's Medical dictionary and the abstract from Shiloni (1993, Cancer Immunology, immunotherapy, Vol. 37, pg 286-292).

Nishimura taught isolating tumor infiltrating lymphocytes (TIL) from colon adenocarcinoma, stimulating the TIL with antigen and transfecting the cells with a chimeric receptor, Mov-γ, that reacts with ovarian tumors ("38 Tumor") (Example 4, col. 35-39; see ¶ bridging col. 37-38; col. 38, lines 11-13; col. 39, Table 8, "38 Mov-TIL" and "38 Tumor"). The TIL have an "endogenous T-cell receptor reactive with a cell, which is allogeneic to the lymphocyte" because non-transduced TIL reacted with murine sarcoma cells (24 JK) in an IFN-γ ELISA (col. 39, Table 8; TIL NV and 24 JK).

While not relied upon for the basis of the rejection, the following evidence is provided to show that the 24 JK cell line is "allogeneic" to the lymphocytes of Nishimura:

"Allogenic" is defined as "having cell types that are antigenically distinct" (see definition from Dorlands Medical Dictionary provided). JK24 cells are "antigenically distinct" because they have low expression of MHC Class I molecules as compared to clone 4JK (see abstract from Shiloni, 1993, Cancer Immunology, immunotherapy, Vol. 37, pg 286-292; lines 3-9).

In a second interpretation, the Mov-γ receptor is also the "endogenous T-cell receptor reactive with a cell, which is allogeneic to the lymphocyte" because Mov-TIL reacted with "38 Tumor" (col. 39, Table 8; Mov-TIL and "38 Tumor"). The term "endogenous" is defined as something produced within the organism or one of its parts (see definition of endogenous in Stedman's medical dictionary and the 112/2nd rejection); the Mov-γ receptor is "endogenous" because it is made within the TIL. The term "allogeneic" is defined as "having cell types that are antigenically distinct" (see definition from Dorland's Medical Dictionary provided); "38 Tumor" cells are "antigenically distinct" because they express increased FBP as compared to 888 MEL, a melanoma cell line (col. 39, Table 8).

In a third interpretation, the Mov-TIL population of Nishimura inherently has a second receptor that is an "endogenous T-cell receptor reactive with a cell, which is allogeneic to the lymphocyte." TIL have a wide array of T-cell receptors; therefore, the TIL of Nishimura would inherently have an endogenous receptors that recognizes mouse cells from a different strain having a different MHC genetic background. Non-transduced TIL (TIL NV) would recognize any mouse cell that had a different MHC molecule, including PBMC, dendritic cells and splenocytes (claims 8, 46, 50, 56, 58).

Therefore, Mov-TIL would also recognize any mouse cell that had a different MHC molecule.

The steps taught by Nishimura are equivalent to the steps of claim 41.

Nishimura taught human TIL could be transduced and used in the invention (col. 38, lines 55-65), which is equivalent to claims 45, 47, 52 and 61.

Applicants argue Nishimura did not teach TIL having dual receptors. Applicants' argument is not persuasive. First, the first and third interpretations of the claims provided by the examiner require two receptors. Second, the claim is not limited to lymphocytes having dual receptors, which is equivalent to the examiner's second interpretation of the claims.

Claims 1, 3, 6-8, 11, 40, 41, 45-47, 50, 52, 56, 58 and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Capon (US Patent 6,407,221, June 18, 2002, filed 6-7-95).

Capon taught a primary human CD8+ lymphocyte transduced with a vector encoding a chimeric receptor that recognizes a tumor antigen (col. 5, lines 26-29; col. 11, lines 41-44; col. 11, line 66, through col. 12, line 8; col 12, line 40; col. 31, line37-44; claim 2). In addition, Capon used the HIV protein gp120 as an antigen in tumor cells; therefore, the gp120 protein is a "tumor antigen" in the teachings of Capon.

The transformed population of cells taught by Capon inherently has a second receptor that is an endogenous T-cell receptor reactive with a cell that is allogeneic to the lymphocyte. The lymphocytes taught by Capon inherently have a wide array of T-

cell receptors and, therefore, must inherently have an endogenous receptors that recognizes cells from a human having a different MHC genetic background. Non-transduced primary human CD8+ lymphocytes would recognize any human cell that had a different MHC molecule, including PBMC, dendritic cells and splenocytes (claims 8, 46, 50, 56, 58). Therefore, the gene-modified primary human CD8+ lymphocytes would also recognize any human cell that had a different MHC molecule.

Claims 1, 3, 6-8, 11, 40, 41, 45-47, 50, 52, 56, 58 and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Capon (US Patent 5,359,046, Oct. 25, 1994, filed 12-9-92).

Capon taught a primary human CD8+ lymphocyte transduced with a vector encoding a chimeric receptor that recognizes a tumor antigen (col. 11, lines 48-56; col. col. 12, line 7-16; col 12, line 45-52; claim 6). In addition, Capon used the HIV protein gp120 as an antigen in tumor cells; therefore, the gp120 protein is a "tumor antigen" in the teachings of Capon.

The transformed population of cells taught by Capon inherently has a second receptor that is an endogenous T-cell receptor reactive with a cell that is allogeneic to the lymphocyte. The lymphocytes taught by Capon inherently have a wide array of T-cell receptors and, therefore, must inherently have an endogenous receptors that recognizes cells from a human having a different MHC genetic background. Non-transduced primary human CD8+ lymphocytes would recognize any human cell that had a different MHC molecule, including PBMC, dendritic cells and splenocytes

(claims 8, 46, 50, 56, 58). Therefore, the gene-modified primary human CD8+ lymphocytes would also recognize any human cell that had a different MHC molecule.

Conclusion

No claim is allowed.

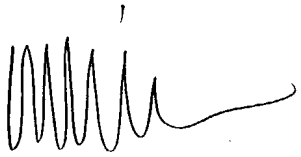
Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at 571-272-0738.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER